

The following provides a brief overview of the policies and processes associated with issuing and responding to a Mixed Analyte Performance Evaluation Program (MAPEP) Letter of Concern, and its significance to the Department of Energy's Consolidated Audit Program (DOECAP).

The MAPEP issues a Letter of Concern to a participating laboratory upon identification of a potential analytical data quality problem in the MAPEP results, in order to help participants identify, investigate, and resolve potential quality issues. Letters of Concern have been issued since 1996, shortly after the beginning of the MAPEP program. A copy of the Letter of Concern is also sent to DOE/contractor oversight Points of Contact (POCs), including DOE Field Office and Headquarters POCs, and contractor Sample Management POCs. Issued to be informative and not punitive, each Letter of Concern states, *"This letter is solely intended to alert your laboratory to a potential quality concern that you may wish to investigate for corrective action."* A Letter of Concern is issued to any participating laboratory that demonstrates:

- "Not Acceptable" performance for a targeted analyte in a given sample matrix for the two most recent test sessions (e.g., Pu-238 in soil test 13 "+N" (+36% bias), Pu-238 in soil test 14 "-N" (-43% bias));
- "Not Acceptable" performance for a targeted analyte in two or more sample matrices for the current test session (e.g., Cs-137 in water test 14 "+N" (+38%), Cs-137 in soil test 14 "+N" (+45%));
- Consistent bias, either positive or negative, at the "Warning" level (greater than +/- 20% bias) for a targeted analyte in a given sample matrix for the two most recent test sessions (e.g., Sr-90 in air filter test 13 "+W" (+26%), Sr-90 in air filter test 14 "+W" (+28%));
- Quality issues (flags other than "Acceptable") that weren't identified by the above criteria for a targeted analyte in a given sample matrix over the last three test sessions (e.g., Am-241 in soil test 12 "-N" (-47%), Am-241 in soil test 13 "+W" (+24%), Am-241 in soil test 14 "-N" (-38%));
- Any other performance indicator and/or historical trending that demonstrate an obvious quality concern (e.g., consistent "False Positive" results for Pu-238 in all tested matrices over the last three test sessions).

A review period (about two weeks) is provided at the close of each MAPEP test session, prior to the release of final results to DOE stakeholders and the general public, when any laboratory may question or appeal performance evaluation results. All laboratories have the opportunity to respond to a Letter of Concern by contacting the MAPEP Coordinator, and many frequently do so. In addition, laboratories can request additional MAPEP standards at any time for verification of measurement processes, and many have utilized this option.

Letters of Concern specifically address an area of significance to the DOECAP, as laboratory participation in performance evaluation (PE) programs is typically assessed during a DOECAP audit. The DOECAP DoD/DOE Quality Systems Manual Ver. 5.1 identifies the corrective action and documentation required for a laboratory to address PE program failure. For two consecutive failures, the laboratory is required to develop and document corrective action(s) to address the cause(s) within 21 days. Corrective action documentation must be available for review during DOECAP audits, and the same documentation should be available for any clients or other stakeholders. If the DOECAP

issues a finding in the area of PE performance, including any finding derived from or associated with a MAPEP Letter of Concern, the laboratory has the opportunity to respond and perform corrective actions through the DOECAP process.

In addition to issuing Letters of Concern, the MAPEP Team provides technical assistance whenever requested, to both MAPEP participants and DOE/contractor oversight personnel. That assistance has helped resolve many quality issues, thereby improving the quality of analytical services and ultimately reducing potential DOE liability. MAPEP Letters of Concern are instrumental in this process by providing a method of communication that focuses attention on analytical performance, and when used as intended, assists laboratories and DOE/contractor oversight personnel avoid potential quality problems and/or correct quality issues in a timely manner.

It is also important to note that the DOE field site management/personnel, and/or its DOE contractor, that enter into a contractual agreement with an analytical laboratory for field data services, have an important responsibility. They are responsible for assuring that the corrective actions needed to remedy the data discrepancy, as identified by the performance evaluation and testing of MAPEP, satisfy the Department's obligations and provide confidence in the quality, validity, and reliability of the analytical data.

Please contact Guy Marlette or Andrew Hathaway for additional information.

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